

REMARKS

Claims 1, 2, 5-10, 29-35, 37, 38, 40, and 62-65 are pending. Claims 3, 4, 11-28, 36, 39, 41-61, 66, and 67 have been cancelled without disclaimer or prejudice thereto. Claims 1, 2, 29, 33, 34, and 37 have been amended. Support for the amendments to the claims may be found in the specification and in the claims as originally filed. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Applicants reserve the right to pursue the claims as originally filed, currently pending, or substantially similar claims in one or more subsequent patent applications.

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejection under 35 U.S.C. § 102

The rejection of claims 1, 2, 10, 32, and 40 under 35 U.S.C. § 102(b) as allegedly being anticipated by Eckerson (U.S. Patent No. 4,865,048) is respectfully traversed.

A claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), cert denied, 465 U.S. 1026 (1984). Applicants respectfully assert that Eckerson does not teach every element of claims 1, 2, 10, 32, and 40, and therefore does not anticipate these claims.

Each of claims 1, 2, 10, 32, and 40 relates to a method of treating nausea and/or vomiting caused by pregnancy, motion sickness, or chemotherapy comprising the steps of applying one or more electrodes to the neck of a patient and stimulating the vagus nerve in the neck of the patient. In contrast, Eckerson does not teach treating nausea and/or vomiting caused by pregnancy, motion sickness, or chemotherapy. Furthermore, the Examiner characterizes Eckerson as allegedly

teaching “plac[ing] the electrodes on the mastoid process in close proximity to the vagus nerve.” Office Action, page 3. Thus, Eckerson also does not teach applying one or more electrodes to the neck of a patient and stimulating the vagus nerve in the neck of the patient, as required in the present invention. Accordingly, for at least these reasons, Eckerson does not teach each and every element of the present invention.

Claims 1, 2, 10, 32, and 40 are in compliance with 35 U.S.C. § 102(b), and Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection under 35 U.S.C. § 103

Claims 1, 2, 5-10, 32, 40, and 62 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Eckerson. Claims 1, 2, 5, 6-9, 29, 30, 31, 33, 40, and 62-64 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Marchal *et al.* (U.S. Patent No. 6,853,862) (“Marchal”). Claims 10 and 32 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Marchal in view of Barrett *et al.* (U.S. Patent No. 6,609,025). Claims 34, 35, 37, and 38 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Marchal in view of Bertolucci (U.S. Patent No. 4,981,146). Applicants respectfully traverse these rejections for the reasons below.

To establish a *prima facie* case of obviousness, the art cited by the Examiner must (1) teach all of the claim limitations; (2) provide a suggestion or motivation to those of ordinary skill in the art to make the claimed invention; and (3) reveal that one of ordinary skill would have a reasonable expectation of success in doing so. *See In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); *see also* M.P.E.P. § 706.02(j). The United States Supreme Court, in *KSR International vs. Teleflex, Inc.*, 127 S.Ct. 1727, 1739 (April 30, 2007), further clarified the requirements for obviousness analysis under 35 U.S.C. § 103(a). The Court noted that the analysis supporting a rejection under 35 U.S.C. § 103(a) should be made *explicit*, and that it was important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed. *See id.*

Applicants respectfully assert that the Examiner has not met the burden of establishing a *prima facie* case of obviousness because a person of ordinary skill in the art would not have arrived at the claimed invention based on the teachings of the cited references. Each of the pending claims relates to a method of treating nausea and/or vomiting caused by pregnancy, motion sickness, or chemotherapy comprising the steps of applying one or more electrodes to the neck of a patient and stimulating the vagus nerve in the neck of the patient. As discussed above, Eckerson does not teach every element of the claimed subject matter.

Marchal does not cure the deficiencies of Eckerson. The Examiner has acknowledged that “Marchal et al. do not disclose applying electrical current to a vagus nerve located in the neck . . .” Office Action, page 5. The Examiner has also recognized that “Marchal et al. do not explicitly discuss application of the method to chemotherapy patients or patients suffering from morning sickness.” *Id.* at page 8. Thus, Marchal does not teach a method of treating nausea and/or vomiting caused by pregnancy, motion sickness, or chemotherapy comprising the steps of applying one or more electrodes to the neck of a patient and stimulating the vagus nerve in the neck of the patient, as required in the present invention.

Barrett and Bertolucci likewise do cure the deficiencies of Eckerson and Marchal. The Examiner characterizes Barrett as allegedly “disclos[ing] that the vagus nerve may be stimulated directly (i.e., with an electrode cuff placed about the nerve), indirectly from an implanted position (i.e., with an electrode implanted remote from the vagus nerve), or indirectly and non-invasively.” *Id.* at page 7 (internal citations omitted). Bertolucci allegedly “discloses that chemotherapy patients and those suffering from motion sickness may benefit from nerve stimulation in the treatment of nausea and/or vomiting.” *Id.* at page 8. However, neither Barrett nor Bertolucci teach a method of treating nausea and/or vomiting caused by pregnancy, motion sickness, or chemotherapy comprising the steps of applying one or more electrodes to the neck of a patient and stimulating the vagus nerve in the neck of the patient, as required in the present invention.

The Examiner alleges that it would have been obvious to place electrodes on the neck of a patient to ensure that the vagus nerve is adequately stimulated. See *id.* at page 3. However, at

the time of filing of the present application, one of ordinary skill in the art would have understood that vagal stimulation is difficult to achieve, can adversely stimulate other organs, and can cause damage to the vagus nerve. *See* Marchal, col. 1, lines 48-51. As such, one of ordinary skill in the art would not have been motivated to place electrodes and apply current on a previously untested/undisclosed location, e.g., on the neck of a patient. In view of the limitations associated with vagal stimulation, one of ordinary skill in the art would not have reasonably expected to successfully practice the claimed invention absent the teachings of the present application.

Accordingly, for at least these reasons, Applicants respectfully assert that the Examiner has not provided sufficient factual basis for concluding that the present invention would have been obvious to a person of ordinary skill in the art. As the Examiner has not established a *prima facie* case of obviousness, reconsideration and withdrawal of the rejections are requested.

Additional Comments

In the Office Action mailed September 15, 2010, the Examiner took Official Notice that “it is old and well-known in the medical nerve stimulator arts to place electrodes either on the surface for non-invasive placement, or implanted within the body for chronic stimulation” (page 4) and that “inductively controlled implantable devices are old and well-known in the medical arts” (*id.*). In the current Office Action, the Examiner asserts that Applicants did not traverse these Official Notices and have therefore admitted that these features are prior art. Applicants respectfully disagree.

The Official Notices were cited by the Examiner in the rejection of claims 5-9 and 62 under 35 U.S.C. § 103(a) in view of Eckerson. Applicants respectfully remind the Examiner that this rejection was traversed in the response filed on January 14, 2011. In traversing the rejection, Applicants contested all aspects of the rejection, including the Official Notices. Applicants reserve the right to further address these Notices in a later response if necessary.

CONCLUSION

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed, or which should have been filed herewith to our Deposit Account No. 04-1105, under Order No. 61612(71699).

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Respectfully submitted,
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